Timely use of Bakri intrauterine balloon tamponade contributes to the effectiveness in controlling severe postpartum hemorrhage

YAPING HU*, LINGJIE CUI*, CHONG ZHANG and FEIFEI CHEN

Department of Obstetrics, Maternal and Child Health Hospital of Hubei Province, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, Hubei 430070, P.R. China

Received October 16, 2023; Accepted February 14, 2024

DOI: 10.3892/etm.2024.12465

Abstract. The aim of the present study was to explore the effectiveness of Bakri intrauterine balloon tamponade (IUBT) in treating severe postpartum hemorrhage (SPPH). A cohort of 198 women with SPPH using IUBT were retrospectively selected. The baseline and maternal outcome characteristics were examined. The results demonstrated that women with SPPH had a high proportion of placenta accrete (53.0%). Bakri IUBT demonstrated a global effectiveness of 84.5% in SPPH treatment, accounting for 82.9% in women with placenta accrete. Compared with women with Bakri failure, women who experienced Bakri success had reduced rates of less use of pre-/post-IUBT intervention, blood transfusion, lower genital tract trauma, estimated blood loss (EBL), and a longer indwelling duration (P<0.05). Logistic regression revealed that the pre-IUBT intervention (OR=3.910; 95% CI: 1.684-9.079; P=0.002) was positively associated with hemostasis success, while lower genital tract trauma was negatively associated with Bakri success (OR=0.091; 95% CI: 0.009-0.894; P=0.040). Moreover, women diagnosed with placenta accrete underwent a greater number of transabdominal placed Bakri IUBT and pre-IUBT interventions than those without placenta accrete (P<0.05). No significant differences were observed in Bakri success, total EBL, pre-/post-IUBT EBL, infused volume of IUBT, IUBT indwelling duration, even the rate of hemostasis, lower genital tract trauma, blood transfusion, post-IUBT intervention, and puerperal fever between women with and without placenta accrete (P>0.05). In conclusion, placenta accrete may be the leading cause of SPPH. Bakri IUBT is an effective and safe measure for SPPH. Pre-IUBT intervention may be predictive of Bakri's success. The timely use of IUBT during labor may mitigate the impact of risk factors identified on PPH.

Correspondence to: Dr Feifei Chen, Department of Obstetrics, Maternal and Child Health Hospital of Hubei Province, Tongji Medical College, Huazhong University of Science and Technology, 745 Wu Luo Road, Hongshan, Wuhan, Hubei 430070, P.R. China
E-mail: 49381389@qq.com

*Contributed equally

Key words: Bakri intrauterine balloon tamponade, effectiveness, severe postpartum hemorrhage, maternal outcomes, influential factor, placenta accrete

Introduction

Severe postpartum hemorrhage (SPPH) occurs in ~1-2% of deliveries (1) and remains the leading global cause of severe maternal morbidity and mortality (2,3). Currently, SPPH is responsible for 25% of the 600,000 annual maternal deaths, accounting for the death toll of 150,000 women annually worldwide (4). Most maternal deaths caused by SPPH occurred within the first 24 h after birth, accounting for 33.9% in Asia (5). Longer hospital duration and higher mortality effects are usually induced by SPPH (6). SPPH may induce long-term negative mental health effects due to the increased risk for post-traumatic stress disorder (7). Although IUBT was introduced to China for the treatment of PPH in 2012, few studies have been reported among women with PPH in China, especially SPPH. Conflicting evidence about the effectiveness of Bakri IUBT was observed (8,9). As China's population ages and the three-child policy is implemented, an increase in the number of elderly pregnant women has been linked to an increased incidence of SPPH (10). The risk factors for PPH vary greatly across studies (11-13), prompting us to conduct additional research to identify the influential factors for SPPH, particularly in a high-risk maternal population.

Currently, there is no gold standard treatment for SPPH (14). Although the definition of SPPH is inconsistent in different guidelines (15-17), a total estimated blood loss (EBL) ≥1,000 ml within the first 24 h is commonly used (18). Emergency postpartum hysterectomy may be unavoidable in women with failed hemostasis and is associated with a high morbidity (19). Among various conservative procedures for controlling PPH, a Bakri IUBT has been recommended in second-line treatment (8). Compared with other conservative interventions, Bakri IUBT has demonstrated remarkable advantages in clinical application, such as minimal local resource requirement, less training and high effectiveness in fertility retention (20). However, conflicting evidence of Bakri IUBT in controlling PPH was reported, and most of the usage of IUBT was empirical (9). The second-line management for SPPH remains challenging due to a lack of evidence. Notably, the evidence for the timing of IUBT insertion on IUBT effectiveness is still lacking.

In the present study, it was aimed to explore Bakri IUBT's effectiveness in treating SPPH. The potential influential factors for Bakri's success among women with SPPH were also analyzed.

Materials and methods

Study subject. A total of 198 eligible participants with SPPH who received Bakri IUBT (Cook Medical) were included between January 2016 and December 2020 in the retrospective cohort study. All participants who received Bakri IUBT with age ≥18 years old, gestation age ≥28 weeks, failure in first-line conservative treatment, and a total of blood loss ≥1,000 ml within the first 24 h were continuously selected in the study. Women with malignant tumors, uterine fibroids, pelvic infections, abortions, or abnormal coagulation were excluded. Among these women, 105 women with placenta accrete were included. Placenta accrete was characterized by all or part of the placenta being invaded or attached abnormally to the scarred myometrium underneath (21,22). Placenta accrete was diagnosed by incomplete placental delivery, confirmed during manual placenta removal. Combining pathological examination with B-ultrasound may also be necessary. In women who gave birth vaginally, the placenta was manually removed if there were no signs of placental delivery at least 30 min after active treatment in the third stage of labor. In women with cesarean section, the placenta was also manually removed if there was no sign of placental detachment after the delivery of the fetus. In some complex cases, a multidisciplinary team was formed to ensure an accurate diagnosis of placenta accrete.

All recruited women with SPPH met the criteria of the guideline of prevention and treatment for postpartum hemorrhage (2023) in China (18). Initially, a first-line uterotonic agent or combined uterine massage was adopted. A Bakri IUBT balloon was used as a second-line option if first-line treatments failed. Bakri's success was defined as successful hemostasis with no post-IUBT intervention. Bakri failure is characterized by any post-IUBT intervention, such as uterine artery embolization (UAE), internal iliac artery embolization (IIAE), and hysterectomy. Informed consent was waived due to the nature of the retrospective study. The present study was approved by the Ethics Committee of the Maternal and Child Health Hospital of Hubei Province (approval no. 2022-IEC-XM073; Wuhan, China), and all procedures performed complied with the Declaration of Helsinki (2013).

Implementation standards of Bakri IUBT. Briefly, the presence of placental residue, birth canal lacerations and uterine vascular bleeding were confirmed before Bakri IUBT placement; ultrasound consultation was also performed if necessary. During cesarean section, a Bakri balloon was inserted from the uterine incision, with the catheter through the cervical opening. The catheter was pulled on both sides of the cervical opening by a midwife, to allow the balloon bottom contact with the cervical opening. In vaginal birth, Bakri's balloon was clamped with toothless oval cervical clamp to pass through the cervical canal and uterine opening until it reached the bottom of the uterus. The catheter was fixed on the women's thigh and the balloon was filled with sterile water. A vaginal examination was performed to ensure the correct placement of the balloon. After Bakri IUBT placement, massaging the uterus or applying pressure to the fundus was avoided. The vaginal posterior fornix was filled with gauze to prevent balloon detachment. Intravenous infusion of oxytocin for 24 h can be adopted to maintain effective uterine contractions. Routine use of antibiotics was administrated to prevent infection. The volume of blood drained by the drainage tube and the height of fundus every h were recorded. The timing of Bakri IUBT withdrawal was based on its hemostatic effect by an experienced physician. Bakri IUBT was placed inside the uterine cavity for up to 24 h, with a maximum indwelling duration of <48 h. After the balloon was completely emptied, the Bakri balloon was gently extracted from the vagina through the cervical opening. Maternal vital signs and vaginal bleeding after removing the balloon were monitored.

Data collection and measures. The maternal clinical characteristics, including baseline data and maternal outcomes of all eligible women, were analyzed. All data were deidentified before analysis. The effectiveness of Bakri IUBT, the maternal outcomes, the related factors for Bakri's success and the effect of IUBT in women with placenta accrete were all explored.

Statistical analysis. Analyses were conducted using SPSS, version 22.0 (IBM Corp). Continuous variables were presented as the mean ± standard deviation (SD) and compared using an unpaired t-test (two-sided). Categorical variables were presented as numbers and percentages and analyzed using the Chi-square test or Fisher's exact test. Logistic regression analysis was conducted to investigate the related factors for Bakri success in women with SPPH, and variables with $P<0.20$ in the univariable analysis were included. $P<0.05$ was considered to indicate a statistically significant difference.

Results

Baseline characteristics analysis in women with Bakri failure and Bakri success. Among the 198 maternal women recruited, 168 had Bakri success (84.5%; 168/198) (Table I). Analysis of baseline data revealed no significant differences in demographic and other baseline parameters such as parity, delivery mode, and past medical history between women with Bakri failure and those with Bakri success (all $P>0.05$). All these women were characterized by a high proportion of gestational age ≥37 weeks (90.4%; 179/198), uterine atony (42.4%; 84/198) and placenta accrete (53.0%; 105/198).

Maternal outcomes analysis in women with Bakri failure and Bakri success. The maternal outcomes of women with Bakri failure and those with Bakri success were analyzed (Table II). Among all these women, the mean duration from delivery to Bakri IUBT insertion was ≥1 h. Women with transvaginally placed Bakri IUBT accounted for 81.3% (161/198), and those with blood transfusion accounted for 80.3% (159/198). Pre-IUBT interventions, such as '8' sutures, toothless oval cervical clamps and arterial ligation, were administrated in 46 (23.2%) women. None required a hysterectomy, and maternal intrapartum fever occurred in two cases. Compared with women with Bakri failure (n=30),

Table I. Baseline characteristics analysis in women with Bakri failure and Bakri success.

Characteristics	Bakri failure (n=30)	Bakri success (n=168)	t/χ^2	P-value
Weight (n, %)	71.8±8.6	72.8±10.9	-1.46	0.14
Maternal age, n (%)			0.85	0.36
<35 years	27 (90.0)	140 (83.3)		
≥35 years	3 (10.0)	28 (16.7)		
Gestational age, n (%)			0.00	0.99
<37 weeks	3 (10.0)	16 (9.5)		
≥37 weeks	27 (90.0)	152 (90.5)		
Parity, n (%)			0.51	0.47
Primipara	23 (76.7)	118 (70.2)		
Multipara	7 (23.3)	50 (29.8)		
Delivery mode, n (%)			0.30	0.59
Vaginal delivery	21 (70.0)	109 (64.9)		
Cesarean section	9 (30.0)	59 (35.1)		
Birth number, n (%)			0.02	0.88
Single births	28 (93.3)	158 (94.0)		
Multiple births	2 (6.7)	10 (6.0)		
Repeat cesarean section, n (%)			1.29	0.26
No	30 (100.0)	161 (95.8)		
Yes	0 (0.0)	7 (4.2)		
Gestational diabetes n, (%)			0.18	0.67
No	30 (100.0)	167 (99.4)		
Yes	0 (0.0)	1 (0.6)		
Gestational hypertension, n (%)			0.09	0.76
No	29 (96.7)	164 (97.6)		
Yes	1 (3.3)	4 (2.4)		
Uterine atony, n (%)			0.84	0.47
No	18 (60.0)	96 (57.1)		
Yes	12 (40.0)	72 (42.9)		
Placenta accrete, n (%)			0.69	0.41
No	12 (40.0)	81 (48.2)		
Yes	18 (60.0)	87 (51.8)		
Placenta previa, n (%)			0.01	0.93
No	28 (93.3)	156 (92.9)		
Yes	2 (6.7)	12 (7.1)		
Preeclampsia, n (%)			0.91	0.34
No	30 (100.0)	163 (97.0)		
Yes	0 (0.0)	5 (3.0)		

women with Bakri success (n=168) exhibited less use of pre-IUBT intervention (χ^2=14.21, P<0.01), lower genital tract trauma (χ^2=3.84; P=0.04), and less total/post-IUBT EBL (t=7.17, P<0.01; t=7.56, P<0.01). A longer IUBT indwelling duration (t=6.85; P<0.01), a higher proportion of indwelling duration ≥6 h (χ^2=106.99; P<0.01), and a lower use of blood transfusion [including the proportion and transfusion volume of red blood cell (RBC), cryoprecipitate and plasma; P<0.01] were also observed in women with Bakri success. Of the women with Bakri failure, 86.7% (26/30) cases received UAE and 13.3% (4/30) cases received IIAE.

Related factors analysis for Bakri success in women with SPPH. The factors associated with Bakri's success in women with SPPH were examined (Table III). The pre-IUBT variables (pre-IUBT EBL, pre-IUBT intervention, lower genital tract trauma and delivery/insertion duration) with P<0.20 from the univariate analyses in the binary logistic regression were included. The pre-IUBT intervention (OR=3.910; 95% CI: 1.684-9.079; P=0.002) was positively associated with hemostasis success, whereas lower genital tract trauma was negatively associated with Bakri success (OR=0.091; 95% CI: 0.009-0.894; P=0.040).

Table II. Maternal outcomes analysis in women with Bakri failure and Bakri success.

Outcomes	Bakri failure (n=30)	Bakri success (n=168)	t/χ^2	P-value
Delivery/insertion duration (Mean ± SD, min)	73.4±58.4	62.1±69.1	-0.69	0.49
Delivery/insertion duration, n (%)			2.58	0.11
<1 h	22 (73.3)	97 (57.7)		
≥1 h	8 (26.7)	71 (42.3)		
IUBT placement method, n (%)			0.04	0.84
Transvaginally	24 (80.0)	137 (81.5)		
Transabdominally	6 (20.0)	31 (18.5)		
Pre-IUBT intervention, n (%)			14.21	<0.01
No	15 (50.0)	137 (81.5)		
Yes	15 (50.0)	31 (18.5)		
Lower genital tract trauma, n (%)			3.84	0.04
No	28 (93.3)	166 (98.8)		
Yes	2 (6.7)	2 (1.2)		
Total EBL	1,682.0±109.0	1,235.6±232.3	7.17	<0.01
Pre-IUBT EBL (Mean ± SD, ml)	1,257.7±73.4	1,179.8±18.4	1.46	0.15
Post-IUBT EBL (Mean ± SD, ml)	424.3±76.4	55.7±52.0	7.56	<0.01
Infused volume (Mean ± SD, ml)	432.0±51.3	418.3±51.3	1.12	0.27
Indwelling time (Mean ± SD, min)	302.5±65.1	1,109.5±28.4	6.85	<0.01
Indwelling duration, n (%)			106.99	<0.01
<6 h	22 (73.3)	5 (3.0)		
≥6 h	8 (26.7)	163 (97.0)		
Post-IUBT intervention, n (%)			178.11	<0.01
None	0 (0.0)	168 (100.0)		
UAE	26 (86.7)	0 (0.0)		
IIAE	4 (13.3)	0 (0.0)		
Blood transfusion, n (%)			5.99	0.01
No	1 (3.3)	38 (22.6)		
Yes	29 (96.7)	130 (77.4)		
RBC (Mean ± SD, U)	5.6±3.2	2.6±1.8	7.56	<0.01
Cryoprecipitate (Mean ± SD, U)	5.0±2.3	1.8±2.1	7.44	<0.01
Plasma (Mean ± SD, ml)	510.0±59.5	195.4±16.3	-5.25	<0.01
Puerperal fever, n (%)			1.90	0.17
No	29 (96.7)	167 (99.4)		
Yes	1 (3.3)	1 (0.6)		

IUBT, intrauterine balloon tamponade; UAE, uterine artery embolization; IIAE, internal iliac artery embolization; SD, standard deviation; EBL, estimate blood loss; RBC, red blood cell.

Analysis of baseline characteristics in women without placenta accrete and those with placenta accrete. Further, baseline characteristics in women without placenta accrete (n=93) and those with placenta accrete (n=105) were compared (Table IV). Women with placenta accrete were characterized by less uterine atony (χ^2=35.27, P<0.01) and more preeclampsia (χ^2=4.52; P=0.03). No significant differences in demographic and other baseline parameters were observed between women without placenta accrete and those with placenta accrete (P>0.05).

Role of Bakri IUBT in women with placenta accrete. The effects of Bakri IUBT on maternal outcomes in women with placenta accrete were analyzed (Table V). A Bakri success rate of 82.9% (87/105) was observed in women with placenta accrete, with no significant difference from that in women (87.1%, 81/93) without placenta accrete (χ^2=0.69, P=0.41). An underlying decreased trend in delivery/insertion duration of IUBT was observed in women with placenta accrete compared with those without placenta accrete (χ^2=1.79; P=0.08). Notably, women with placenta accrete had more transabdominally placed Bakri IUBT (χ^2=9.37; P<0.01) and pre-IUBT intervention (χ^2=4.96; P=0.03) than those without placenta accrete (P<0.05). No significant differences were observed in total EBL, pre-/post-IUBT EBL, infused volume of IUBT, IUBT

Table III. Related factors analysis for Bakri success in women with SPPH by logistic regression.

Variables	β	S.E.	Wald	df	P-value	OR	95% CI	
							Lower	Upper
Pre-IUBT EBL	-0.001	0.001	1.341	1	0.247	0.999	0.998	1.001
Pre-IUBT intervention	1.363	0.430	10.062	1	0.002	3.910	1.684	9.079
Lower genital tract trauma	-2.394	1.164	4.229	1	0.040	0.091	0.009	0.894
Delivery/insertion duration	0.789	0.509	2.402	1	0.121	0.454	0.167	1.232

The pre-IUBT variables in the univariate analysis results with P<0.20 were included in the logistic regression. OR, odds ratio; CI, confidence interval; IUBT, intrauterine balloon tamponade; SPPH, severe postpartum hemorrhage; EBL, estimate blood loss.

indwelling duration, hemostasis rate, lower genital tract trauma, blood transfusion, post-IUBT intervention and puerperal fever between women with placenta accrete and those without placenta accrete (P>0.05).

Discussion

SPPH remains a life-threatening condition that causes significant maternal morbidity and mortality. The current cohort study retrospectively examined the continuous clinical data of 198 women with SPPH who underwent IUBT in a single center. The present findings demonstrated that Bakri IUBT showed a global effectiveness of 84.5% (168/198) in SPPH treatment. Even in women with placenta accrete, a Bakri success rate of 82.9% was observed. In the current study, placenta accrete may be the leading cause of SPPH, accounting for 53.0% (105/198). Logistic regression revealed that Bakri's success was positively associated with the pre-IUBT intervention (OR=3.910; 95% CI: 1.684-9.079; P=0.002) and negatively associated with lower genital tract trauma (OR=0.091; 95% CI: 0.009-0.894; P=0.040).

The effectiveness of IUBT in controlling postpartum bleeding has been the focus of research, and conflicting evidence was reported (8,9). The findings of the present study were consistent with previous studies which demonstrated that Bakri IUBT effectively managed SPPH (23,24). Conversely, IUBT was reported to be less effective for PPH treatment after vaginal or cesarean delivery in the study of Said Ali *et al* (8). In a randomized controlled trial by Dumont *et al* (25), IUBT and misoprostol vs. misoprostol alone may increase the risk of mortality and blood loss. The limited evidence concerning Chinese PPH women was searched, which supported the present findings (26,27). In a retrospective study conducted in a welfare institution in Shanghai, the Bakri IUBT resulted in an 87.3% success rate in women with PPH (124 of 142) (26). Bakri IUBT revealed a 91.7% effectiveness in the study of Wang *et al* (27). Liu *et al* (28) reviewed 106 SPPH women managed with IUBT, and the result demonstrated a 70.8% effectiveness of IUBT (75/106). In the present study, the overall success rate of Bakri IUBT for SPPH was 84.5% (168/198), even accounting for 82.9% in women with placenta accrete. The varied effectiveness may be significantly impacted by the sample recruited. For example, in the study of Liu *et al* (28), the women were from tertiary hospitals in first-tier cities of China with a higher proportion of cesarean delivery and a lower proportion of placenta accrete spectrum. Similarly, as reported by Wang *et al* (27), only 16.5% (67/407) women with vaginal delivery were enrolled, and 83.5% (340/407) received cesarean delivery. In the present study, characteristic analysis of SPPH women revealed that vaginal delivery accounted for 65.7%, placenta accrete accounted for 53.0%, and uterine atony accounted for 42.4%. The developed protocol for PPH may explain the high effectiveness of IUBT in the current study since its introduction in 2016. The use of Bakri IUBT was advocated as more active, which played a vital role in hemostasis by exerting local compression pressure on the vessels of the placental bed (29). The present findings demonstrated that Bakri IUBT effectively managed SPPH, even in women with placenta accrete.

Placenta accrete is a complication of obstetrics characterized by abnormal invasion or adherence in whole or parts to the myometrium. Placenta accrete is a pathological condition of the placenta caused by the absence or defect of decidual tissue, adhesion, invasion, or even penetration of placental villous tissue into the uterine muscle layer, including three grades, namely, 'accreta', 'increta' and 'percreta' (21). This prevents placental detachment, resulting in a substantially increased risk of placenta accrete spectrum, severe PPH, maternal morbidity and mortality (30,31). In past decades, the incidence of placenta accrete has increased due to the increase in *in vitro* fertilization techniques and cesarean section (32,33). Besides, a previous history of other uterine surgery, induced labor, curettage, uterine inflammation, or infection can lead to placenta accrete (34). There is no doubt that women with placenta accrete are at a high risk of SPPH, particularly those who have had the placenta manually removed. Placenta accrete can indicate massive bleeding or peripartum hysterectomy, therefore controlling bleeding is critical. In the present study, placenta accrete was present in >50% of cases, suggesting that placenta accrete was the leading cause of SPPH. The reason may be that Maternal and Child Health Hospital of Hubei Province received numerous women with placenta accrete from other hospitals. Further investigation into the Bakri IUBT influence demonstrated a high Bakri success rate in women with placenta accrete (82.9%, 87/105), showing no significant difference with those without placenta accrete (87.1%, 81/93). The result revealed that IUBT was effective for SPPH, even in women who had placenta accrete. Notably, a higher pre-IUBT intervention and transabdominally placed IUBT in women with placenta accrete were observed, suggesting that pre-IUBT was in favor of Bakri's success.

Table IV. Characteristics comparison between women with placenta accrete and those without placenta accrete.

Characteristics	Without placenta accrete (n=93)	With placenta accrete (n=105)	t/χ^2	P-value
Weight, n (%)	72.3±9.7	72.6±10.3	-1.31	0.34
Weight, n (%)			1.03	0.31
<70 kg	35 (37.6)	47 (44.8)		
≥70 kg	58 (62.4)	58 (55.2)		
Maternal age, n (%)			1.95	0.16
<35 years	82 (88.2)	85 (81.0)		
≥35 years	11 (11.8)	20 (19.0)		
Gestational age, n (%)			0.01	0.97
<37 weeks	9 (9.7)	10 (9.5)		
≥37 weeks	84 (90.3)	95 (90.5)		
Parity, n (%)			2.25	0.13
Primipara	71 (76.3)	70 (66.7)		
Multipara	22 (23.7)	35 (33.3)		
Delivery mode, n (%)			0.00	0.99
Vaginal delivery	61 (65.6)	69 (65.7)		
Cesarean section	32 (34.4)	36 (34.3)		
Birth number, n (%)			0.66	0.42
Single births	86 (92.5)	100 (95.2)		
Multiple births	7 (7.5)	10 (4.8)		
Repeat cesarean section, n (%)			1.73	0.19
No	88 (94.6)	103 (98.1)		
Yes	5 (5.4)	2 (1.9)		
Gestational diabetes, n (%)			1.13	0.29
No	92 (98.9)	105 (100.0)		
Yes	1 (1.1)	0 (0.0)		
Gestational hypertension, (n, %)			1.49	0.22
No	92 (98.9)	101 (96.2)		
Yes	1 (1.1)	4 (3.8)		
Uterine atony, n (%)			35.27	<0.01
No	3 (3.2)	40 (38.1)		
Yes	90 (96.8)	65 (61.9)		
Placenta previa, n (%)			0.63	0.43
No	85 (91.4)	99 (94.3)		
Yes	8 (8.6)	6 (5.7)		
Preeclampsia, n (%)			4.52	0.03
No	93 (100.0)	100 (95.2)		
Yes	0 (0.0)	5 (4.8)		

The present study analyzed the maternal outcomes and related factors for Bakri success in women with SPPH. In clinical practice, placental dissection usually occurs within 30 min after delivery time, and the subsequent postpartum bleeding could be remarkably rapid in some cases, including those whose placenta was manually removed. According to the guideline, IUBT was applied after the failure of the first-line conservative treatment (uterotonic agent and uterine massage), with a mean delivery/insertion duration >1 h. As demonstrated in the present study, women with Bakri failure had more significant total/post-IUBT EBL than those with Bakri success, even the pre-IUBT EBL, despite no differences. The results indicated that pre-IUBT hemostatic impairment and hemodynamic instability existed in the early phase of SPPH, and the situation of women with Bakri failure was even worse. As expected, pre-IUBT interventions (such as UAE, figure-of-8 closure, artery ligation, and toothless oval cervical clamp technique) were more common in women with Bakri failure than those with Bakri success (50.0 vs. 18.5%). Temporary uterine artery occlusion proved a theoretical fertility advantage (35). A pre-IUBT intervention may improve hemodynamic instability, ensuring enough hemodynamic stability for delivery,

Table V. Maternal outcomes analysis in women without placenta accrete and those with placenta accrete.

Characteristics	Without placenta accrete (n=93)	With placenta accrete (n=105)	t/χ^2	P-value
Hemostasis			0.69	0.41
No	12 (12.9)	18 (17.1)		
Yes	81 (87.1)	87 (82.9)		
Delivery/insertion duration, (Mean ± SD, min)	82.8±86.3	61.9±78.7	1.79	0.08
IUBT placement method, n (%)			9.37	<0.01
Transvaginally	84 (90.3)	77 (73.3)		
Transabdominally	9 (9.7)	28 (26.7)		
Pre-IUBT intervention, n (%)			4.96	0.03
No	78 (83.9)	74 (70.5)		
Yes	15 (16.1)	31 (29.5)		
Lower genital tract trauma, n (%)			1.28	0.26
No	90 (96.8)	104 (99.0)		
Yes	3 (3.2)	2 (1.0)		
Total EBL	1294.2±338.9	1311.2±328.2	-0.34	0.74
Pre-IUBT EBL (Mean ± SD, ml)	1196.1±287.8	1187.6±253.6	0.22	0.83
Post-IUBT EBL (Mean ± SD, ml)	98.0±19.6	123.6±31.6	-0.84	0.40
Infused volume (Mean ± SD, ml)	418.3±58.8	4122.2±65.1	-0.44	0.66
Indwelling duration, n	994.3±442.5	980.9±489.7	0.20	0.84
<6 h	11 (11.8)	16 (15.2)	0.49	0.49
≥6 h	82 (88.2)	89 (84.8)		
Post-IUBT intervention, n (%)			0.43	0.51
None	81 (87.1)	87 (82.9)		
UAE	10 (10.8)	16 (15.2)		
IIAE	2 (2.2)	2 (1.9)		
Blood transfusion, n (%)			0.92	0.37
No	21 (22.6)	18 (17.1)		
Yes	72 (77.4)	87 (82.9)		
Red blood cells (Mean ± SD, U)	3.0±2.6	3.1±2.0	-0.32	0.75
Cryoprecipitate (Mean ± SD, U)	2.3±1.5	2.3±1.4	0.05	0.96
Plasma (Mean ± SD, ml)	251.6±81.8	235.2±34.8	0.45	0.66
Puerperal fever, n (%)			0.01	0.93
No	92 (98.9)	167 (99.0)		
Yes	1 (1.1)	1 (1.0)		

IUBT, intrauterine balloon tamponade; EBL, estimated blood loss; UAE, uterine artery embolization; IIAE, internal iliac artery embolization.

especially in women with Bakri failure. Further logistic regression revealed that the pre-IUBT intervention was predictive of Bakri's success, but lower genital tract trauma was not.

The timing of IUBT insertion may greatly influence Bakri's success, but the evidence is lacking. Interestingly, women with Bakri failure had a lower proportion of women with delivery/insertion duration ≥1 h and a little longer delivery/insertion duration than those with Bakri success (though no differences were observed). The result highlighted the importance of early use of IUBT insertion and the doctor's favorable sense of timing. In the study of Wang *et al* (36), the timely insertion of IUBT after delivery could effectively enhance the perinatal outcome of PPH and reduce the cesarean section rate. Similarly, Wang *et al* (27) reported that a combination of rapid diagnosis of PPH with early IUBT use was more effective in managing PPH. Indeed, the indwelling time of IUBT can be influenced by the timing of insertion. The current findings revealed that women with Bakri success had a longer indwelling time and a higher proportion of indwelling duration ≥6 h, indicating a positive correlation between long indwelling time and good maternal outcome. Thus, 4-6 h of IUBT duration was recommended to achieve hemostasis by Green-top Guideline (37). In a study by Dorkham *et al* (38), IUBT failure occurred within 6 h after IUBT insertion. Einerson *et al* (39) reported that the indwelling duration of 12 h is likely sufficient for controlling bleeding and that ≥12 h

may result in more postpartum fever and longer hospitalization duration. As identified by Alouini *et al* (40), Bakri IUBT proved to be an efficient tool for SPPH with a mean indwelling duration of 7 h (range 5-9 h). According to the manufacturer's instructions, Bakri IUBT was recommended to be removed within 24 h primarily to prevent infection and tissue necrosis. The differences in the indwelling time of the IUBT may be due to continuous bleeding that cannot be controlled with other techniques. The heterogeneity of PPH management may also be one of the reasons. From another perspective, the shorter indwelling duration may also reflect the early prolapse of IUBT from the uterus due to uterine cavity enlargement and cervical opening relaxation. The present findings suggested that early use of IUBT may be beneficial to successful hemostasis. Timely monitoring and management of balloon deflation is critical. More research is needed to investigate the effects of IUBT insertion and indwelling duration on maternal outcomes.

Inadequate filling of the uterine cavity may be one possible reason for Bakri's failure. In the study of Olsen *et al* (41), the maximum capacity of IUBT failed to stop bleeding in 50% of women with Bakri failure (16% balloon out of the uterus), and the most complaints were extrusion of the balloon, continued atony and post-IUBT continued bleeding (41). However, Alouini *et al* (40) reported Bakri IUBT with a mean filling volume of 350 ml (range 205-450 ml) and an effectiveness of 88% in women with SPPH. In the present study, no significant difference in the infused volume of IUBT was observed between women with Bakri failure (432 ml) and those with Bakri success (418 ml). It was hypothesized that the balloon infusion volume may not associate with the hemostasis effectiveness and that balloon prolapse may be untenable for Bakri failure. However, this point needs to be verified in further studies.

Transfusion is the primary treatment for SPPH. Bakri IUBT was reported to be associated with reduced blood transfusion and increased hemoglobin and hematocrit (42). Of all the women recruited in the current study, 80.3% (159/198) received blood transfusions, including RBC transfusion (80.3%), cryoprecipitate transfusion (56.6%) and plasma transfusion (58.6%). Women with Bakri failure also had a significantly higher transfusion volume and proportion of RBC, cryoprecipitate and plasma transfusions than those with Bakri success. The blood transfusion data in the Maternal and Child Health Hospital of Hubei Province may reflect the real status of the patient in China. Notably, the developed protocol for PPH played an essential role in blood transfusion, which could improve the prognosis of mothers. The massive hemostatic volume, the physical attributes of the delivery woman, and the related risk factors should all be considered.

Most PPH-related mortality deaths are considered preventable, which highlights the critical importance of risk assessment and early intervention (43,44). As described in the present study, none required postpartum hysterectomy, and women with IUBT failure immediately received a post-IUBT intervention. The uterine artery originated from a branch of the IIA, prone to spasms. IIA is a branch of the common iliac artery located at the lumbosacral intervertebral disc in front of the sacroiliac joint. In a meta-analysis by Sathe *et al* (45), using embolization for PPH treatment was of great effectiveness with a success rate of 89%. Kim *et al* (46) revealed UAE to be a safe and effective PPH treatment method with a success rate of 99.1%. UAE was also recommended in women with secondary PPH (47) combined with the placenta accrete spectrum (48). The findings of the present study indicated that an immediate post-IUBT intervention was an effective alternative to hysterectomy. For these high-risk women, preparing a detailed hemostasis plan in advance is improved. More studies are needed to verify the present findings.

Nevertheless, there are several limitations to the present study. All women were retrospectively collected from a single center, which was challenging to avoid sample selection bias and a relatively small sample size. However, the current findings added to the existing limited evidence of pre-IUBT intervention and Bakri IUBT in women with placenta accrete. More studies are still warranted to explore the potential effects of pre-IUBT intervention, lower genital tract trauma, and Bakri IUBT insertion timing on IUBT effectiveness.

In conclusion, placenta accrete may be the leading cause of SPPH. Bakri IUBT effectively and safely managed SPPH in real-world settings in China, even in women with placenta accrete. The pre-IUBT intervention and lower genital tract trauma were associated with the effectiveness of IUBT. The pre-IUBT intervention predicts Bakri's success, even in women with placenta accrete. The timely use of IUBT during labor may mitigate the effects of risk factors identified on PPH. The current findings support the use of Bakri IUBT for SPPH administration in obstetric practice.

Acknowledgements

Not applicable.

Funding

The present study was supported by the General Program from Maternal and Child Health Hospital of Hubei Province (grant no. 2021SFYM021).

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

YH and FC provided input into the concept and design of the study. YH, LC and CZ collected and assembled the data, wrote the article and critically revised the article. YH and FC confirmed the authenticity of all the raw data. All authors read and approved the final version of the manuscript.

Ethics approval and consent to participate

The present study was conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines. The study was approved by the Ethics Committee of Maternal and Child Health Hospital of Hubei Province (approval no. 2022-IEC-XM073; Wuhan, China). Consents were waived from individuals due to the retrospective nature of the study.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

References

1. Corvino F, Giurazza F, Vallone M, Mosca S, Fischer MJ, Corvino A and Niola R: Postpartum hemorrhage: Rescue. Semin Ultrasound CT MR 42: 75-84, 2021.
2. Say L, Chou D, Gemmill A, Tunçalp Ö, Moller AB, Daniels J, Gülmezoglu AM, Temmerman M and Alkema L: Global causes of maternal death: A WHO systematic analysis. Lancet Glob Health 2: e323-e333, 2014.
3. GBD 2017 Causes of Death Collaborators: Global, regional, and national age-sex-specific mortality for 282 causes of death in 195 countries and territories, 1980-2017: A systematic analysis for the global burden of disease study 2017. Lancet 392: 1736-1788, 2018.
4. Sentilhes L, Vayssière C, Deneux-Tharaux C, Aya AG, Bayoumeu F, Bonnet MP, Djoudi R, Dolley P, Dreyfus M, Ducroux-Schouwey C, *et al*: Postpartum hemorrhage: Guidelines for clinical practice from the French college of gynaecologists and obstetricians (CNGOF): In collaboration with the French society of anesthesiology and intensive care (SFAR). Eur J Obstet Gynecol Reprod Biol 198: 12-21, 2016.
5. Khan KS, Wojdyla D, Say L, Gülmezoglu AM and Van Look PF: WHO analysis of causes of maternal death: A systematic review. Lancet 367: 1066-1074, 2006.
6. Marshall AL, Durani U, Bartley A, Hagen CE, Ashrani A, Rose C, Go RS and Pruthi RK: The impact of postpartum hemorrhage on hospital length of stay and inpatient mortality: A national inpatient Sample-based analysis. Am J Obstet Gynecol 217: 344.e1-344.e6, 2017.
7. van Steijn ME, Scheepstra KWF, Zaat TR, van Rooijen DE, Stramrood CAI, Dijksman LM, Valkenburg-van den Berg AW, Wiltenburg W, van der Post JAM, Olff M and van Pampus MG: Severe postpartum hemorrhage increases risk of posttraumatic stress disorder: A prospective cohort study. J Psychosom Obstet Gynaecol 42: 335-345, 2021.
8. Said Ali A, Faraag E, Mohammed M, Elmarghany Z, Helaly M, Gadallah A, Taymour MA, Ahmad Y, Ibrahim Eissa A, Ibrahim Ogila A, *et al*: The safety and effectiveness of Bakri balloon in the management of postpartum hemorrhage: a systematic review. J Matern Fetal Neonatal Med 34: 300-307, 2021.
9. Suarez S, Conde-Agudelo A, Borovac-Pinheiro A, Suarez-Rebling D, Eckardt M, Theron G and Burke TF: Uterine balloon tamponade for the treatment of postpartum hemorrhage: A systematic review and meta-analysis. Am J Obstet Gynecol 222: 293.e1-293.e52, 2020.
10. Sheen JJ, Wright JD, Goffman D, Kern-Goldberger AR, Booker W, Siddiq Z, D'Alton ME and Friedman AM: Maternal age and risk for adverse outcomes. Am J Obstet Gynecol 219: 390.e1-390.e15, 2018.
11. Liu CN, Yu FB, Xu YZ, Li JS, Guan ZH, Sun MN, Liu CA, He F and Chen DJ: Prevalence and risk factors of severe postpartum hemorrhage: A retrospective cohort study. BMC Pregnancy Childbirth 21: 332, 2021.
12. Nyfløt LT, Sandven I, Stray-Pedersen B, Pettersen S, Al-Zirqi I, Rosenberg M, Jacobsen AF and Vangen S: Risk factors for severe postpartum hemorrhage: A case-control study. BMC Pregnancy Childbirth 17: 17, 2017.
13. Butwick AJ, Ramachandran B, Hegde P, Riley ET, El-Sayed YY and Nelson LM: Risk factors for severe postpartum hemorrhage after cesarean delivery: Case-control studies. Anesth Analg 125: 523-532, 2017.
14. Collins P, Abdul-Kadir R and Thachil J; Subcommittees on Women' s Health Issues in Thrombosis and Haemostasis and on Disseminated Intravascular Coagulation: Management of coagulopathy associated with postpartum hemorrhage: Guidance from the SSC of the ISTH. J Thromb Haemost 14: 205-210, 2016.
15. Escobar MF, Nassar AH, Theron G, Barnea ER, Nicholson W, Ramasauskaite D, Lloyd I, Chandraharan E, Miller S, Burke T, *et al*: FIGO recommendations on the management of postpartum hemorrhage 2022. Int J Gynaecol Obstet 157 (Suppl 1): S3-S50, 2022.
16. Muñoz M, Stensballe J, Ducloy-Bouthors AS, Bonnet MP, De Robertis E, Fornet I, Goffinet F, Hofer S, Holzgreve W, Manrique S, *et al*: Patient blood management in obstetrics: Prevention and treatment of postpartum haemorrhage. A NATA consensus statement. Blood Transfus 17: 112-136, 2019.
17. WHO Guidelines Approved by the Guidelines Review Committee. In: WHO Recommendations for the Prevention and Treatment of Postpartum Haemorrhage. World Health Organization Copyright© 2012, World Health Organization, Geneva, 2012.
18. Obstetrics Subgroup, Chinese Society of Obstetrics and Gynecology, Chinese Medical Association; Chinese Society of Perinatal Medicine, Chinese Medical Association: Guidelines for prevention and treatment of postpartum hemorrhage (2023). Zhonghua Fu Chan Ke Za Zhi 58: 401-409, 2023 (In Chinese).
19. Huque S, Roberts I, Fawole B, Chaudhri R, Arulkumaran S and Shakur-Still H: Risk factors for peripartum hysterectomy among women with postpartum haemorrhage: Analysis of data from the WOMAN trial. BMC Pregnancy Childbirth 18: 186, 2018.
20. Doumouchtsis SK, Papageorghiou AT and Arulkumaran S: Systematic review of conservative management of postpartum hemorrhage: What to do when medical treatment fails. Obstet Gynecol Surv 62: 540-547, 2007.
21. Publications Committee, Society for Maternal-Fetal Medicine; Belfort MA: Placenta accreta. Am J Obstet Gynecol 203: 430-439, 2010.
22. Jauniaux E and Bhide A: Prenatal ultrasound diagnosis and outcome of placenta previa accreta after cesarean delivery: A systematic review and meta-analysis. Am J Obstet Gynecol 217: 27-36, 2017.
23. Revert M, Rozenberg P, Cottenet J and Quantin C: Intrauterine balloon tamponade for severe postpartum hemorrhage. Obstet Gynecol 131: 143-149, 2018.
24. Gauchotte E, De La Torre M, Perdriolle-Galet E, Lamy C, Gauchotte G and Morel O: Impact of uterine balloon tamponade on the use of invasive procedures in severe postpartum hemorrhage. Acta Obstet Gynecol Scand 96: 877-882, 2017.
25. Dumont A, Bodin C, Hounkpatin B, Popowski T, Traoré M, Perrin R and Rozenberg P: Uterine balloon tamponade as an adjunct to misoprostol for the treatment of uncontrolled postpartum haemorrhage: A randomised controlled trial in Benin and Mali. BMJ Open 7: e016590, 2017.
26. Guo Y, Hua R, Bian S, Xie X, Ma J, Cai Y, Sooranna SR and Cheng W: Intrauterine Bakri balloon and vaginal tamponade combined with abdominal compression for the management of postpartum hemorrhage. J Obstet Gynaecol Can 40: 561-565, 2018.
27. Wang D, Xu S, Qiu X, Zhu C, Li Z, Wang Z, Hou H, Gao Y, Wang X, He P, *et al*: Early usage of Bakri postpartum balloon in the management of postpartum hemorrhage: A large prospective, observational multicenter clinical study in South China. J Perinat Med 46: 649-656, 2018.
28. Liu C, Gao J, Liu J, Wang X, He J, Sun J, Liu X and Liao S: Predictors of failed intrauterine balloon tamponade in the management of severe postpartum hemorrhage. Front Med (Lausanne) 8: 656422, 2021.
29. Kong CW and To WWK: Intraluminal pressure of uterine balloon tamponade in the management of severe post-partum hemorrhage. J Obstet Gynaecol Res 44: 914-921, 2018.
30. Collins SL, Alemdar B, van Beekhuizen HJ, Bertholdt C, Braun T, Calda P, Delorme P, Duvekot JJ, Gronbeck L, Kayem G, *et al*: Evidence-based guidelines for the management of abnormally invasive placenta: recommendations from the international society for abnormally invasive placenta. Am J Obstet Gynecol 220: 511-526, 2019.
31. Jauniaux E, Ayres-de-Campos D, Langhoff-Roos J, Fox KA and Collins S; FIGO Placenta Accreta Diagnosis and Management Expert Consensus Panel: FIGO classification for the clinical diagnosis of placenta accreta spectrum disorders. Int J Gynaecol Obstet 146: 20-24, 2019.
32. Capriglione S, Ettore C, Terranova C, Plotti F, Angioli R, Ettore G and Gulino FA: Analysis of ultrasonographic and hystopathologic features of placental invasiveness in vitro fertilization (IVF) pregnancies: A prospective study. J Matern Fetal Neonatal Med 35: 5631-5638, 2022.

33. Hong L, Chen A, Chen J, Li X, Zhuang W, Shen Y, Dai Q and Zhang L: The clinical evaluation of IIA balloon occlusion in caesarean delivery for patients with PAS: A retrospective study. BMC Pregnancy Childbirth 22: 103, 2022.
34. Jauniaux E, Collins S and Burton GJ: Placenta accreta spectrum: Pathophysiology and evidence-based anatomy for prenatal ultrasound imaging. Am J Obstet Gynecol 218: 75-87, 2018.
35. Brown M, Hong M Jr and Lindquist J: Uterine artery embolization for primary postpartum hemorrhage. Tech Vasc Interv Radiol 24: 100727, 2021.
36. Wang Y, Xiao C, Zhang N and Sun G: Performance of Bakri balloon tamponade in controlling postpartum hemorrhage. Am J Transl Res 15: 2268-2279, 2023.
37. No authors listed: Prevention and management of postpartum haemorrhage: Green-top guideline no. 52. BJOG 124: e106-e149, 2017.
38. Dorkham MC, Epee-Bekima MJ, Sylvester HC and White SW: Experience of Bakri balloon tamponade at a single tertiary centre: A retrospective case series. J Obstet Gynaecol 41: 854-859, 2021.
39. Einerson BD, Son M, Schneider P, Fields I and Miller ES: The association between intrauterine balloon tamponade duration and postpartum hemorrhage outcomes. Am J Obstet Gynecol 216: 300.e1-300.e5, 2017.
40. Alouini S, Bedouet L, Ramos A, Ceccaldi C, Evrard ML and Khadre K: Bakri balloon tamponade for severe post-partum haemorrhage: Efficiency and fertility outcomes. J Gynecol Obstet Biol Reprod (Paris) 44: 171-175, 2015 (In French).
41. Olsen R, Reisner DP, Benedetti TJ and Dunsmoor-Su RF: Bakri balloon effectiveness for postpartum hemorrhage: A 'real world experience'. J Matern Fetal Neonatal Med 26: 1720-1723, 2013.
42. Soltan MH, Mohamed A, Ibrahim E, Gohar A and Ragab H: El-menia air inflated balloon in controlling atonic post partum hemorrhage. Int J Health Sci (Qassim) 1: 53-59, 2007.
43. Main EK, McCain CL, Morton CH, Holtby S and Lawton ES: Pregnancy-related mortality in California: Causes, characteristics, and improvement opportunities. Obstet Gynecol 125: 938-947, 2015.
44. Ruppel H, Liu VX, Gupta NR, Soltesz L and Escobar GJ: Validation of postpartum hemorrhage admission risk factor stratification in a large obstetrics population. Am J Perinatol 38: 1192-1200, 2021.
45. Sathe NA, Likis FE, Young JL, Morgans A, Carlson-Bremer D and Andrews J: Procedures and uterine-sparing surgeries for managing postpartum hemorrhage: A systematic review. Obstet Gynecol Surv 71: 99-113, 2016.
46. Kim MJ, Kim IJ, Kim S and Park IY: Postpartum hemorrhage with uterine artery embolization: The risk of complications of uterine artery embolization. Minim Invasive Ther Allied Technol 31: 276-283, 2022.
47. Loya MF, Garcia-Reyes K, Gichoya J and Newsome J: Uterine artery embolization for secondary postpartum hemorrhage. Tech Vasc Interv Radiol 24: 100728, 2021.
48. Jeon GU, Jeon GS, Kim YR, Ahn EH and Jung SH: Uterine artery embolization for postpartum hemorrhage with placenta accreta spectrum. Acta Radiol 64: 2321-2326, 2023.